JAN 8 2002

K014083

510(K) SUMMARY

Date: November 30, 2001

Sponsor: Haemonetics Corporation
400 Wood Road
Braintree, MA 02184

Contact: John Sokolowski
Tel: (781) 356-9488
Fax: (781) 356-3558

Proprietary Name:

Haemonetics Cell Saver 5 Autologous Blood Recovery System

Haemonetics List No. 291A - Haemonetics Corporation Basic Mini Volume (70mL) Cell Saver 5 Bowl Set

Haemonetics List No. 242 10L Waste Bag

Classification Name: Autotransfusion Apparatus (21 CFR 868.5830- Class II)

Empty container for the collection and processing of blood and blood components (21 CFR 864.9100)

Common Name: Cell Saver 5
LN291A Disposable Set with 70mL bowl

LN242 10L Replacement Waste Bag

List No	Predicate Device	Reference
CS5 with Cell Salvage and Sequestration Protocol Software Revision K	CS5 with Cell Salvage and Sequestration Protocol Software Revision -	K932890
LN291A Haemonetics Basic Mini Volume (70 mL) Cell Saver 5 Bowl Set	• LN261 Haemonetics Basic Low Volume High Speed Cell Saver 5 Bowl Set (125mL bowl) • LN263 Haemonetics Basic High Speed Cell Saver 5 Bowl Set (225mL bowl)	• K932890
LN242 10L Waste Bag	• LN246 10L Waste Bag	• Pre-amendment

DEVICE DESCRIPTION

Modification to an Existing Device

This Special 510(k) premarket notification describes a modification to Haemonetics' currently legally marketed CELL SAVER 5 SYSTEM and the Cell Saver 5 Protocols and associated disposable sets. The proposed modifications involve the addition of a new smaller volume, blow molded bowl disposable set, the LN291A Basic Mini Volume (70mL) Cell Saver 5 Bowl Set and the associated software and hardware changes required to accommodate the smaller volume set. It also includes the addition of an alternate 10L waste bag, LN242. **The intended use of the modified device is the same as for the predicate device and has not changed as result of the changes in software for the Cell Salvage and Sequestration Protocols.**

Additionally, the design configuration, material composition, manufacturing methods and operational principles for the changed device are equivalent to those of the predicate device.

Intended Use

The Cell Saver 5 Autologous Blood Recovery System is intended for use as an autotransfusion apparatus in conjunction with the Cell Salvage and Sequestration Protocols and single use sterile disposable sets. The Cell Saver 5 Autologous Blood Recovery System is intended for use to recover blood shed during or subsequent to an operation or as a result of trauma, processing the blood by a centrifugation and washing procedure, and pumping this processed red cell product to either a bag for gravity reinfusion into the patient or to the arterial line of an extracorporeal circuit for reinfusion into the patient. The intended use of the Sequestration Protocol is to collect an autologous preoperative platelet rich plasma product.

LN291A Haemonetics Basic Mini Volume (70mL) Cell Saver 5 Bowl Set is a functionally closed systems intended to be used to perform cell salvage using the CS5 Autologous Blood Recovery System.

LN242 10L Waste Bag is intended to be used as an alternate waste bag with the CS5 Autologous Blood Recovery System.

DESIGN CONTROL ACTIVITIES

For the production, design, manufacturing and worldwide marketing of automated blood component collection systems, Haemonetics has established and is operating under a quality system that is based upon the requirements of the US Food and Drug Administration's Quality System Regulation, International Organization for Standardization's ISO 9001, the European Committee for Standardization's EN 46001, and the Medical Device Directive 93/42/EEC.

In accordance with Haemonetics' Quality System, potential risks associated with the software modifications were identified. Verification testing has been performed and demonstrated that the performance of the modified device is not adversely affected by the software changes.

CONCLUSION

The Cell Saver 5 Autologous Blood Recovery System, the Cell Saver 5 Protocols, software revision K, and its associated disposable set LN291A are substantially equivalent to legally marketed devices. The proposed modifications include the addition of the LN291A Basic Mini Volume (70mL) Cell Saver 5 Disposable Bowl Set and the associated software and hardware changes to the Cell Saver 5 System.

The LN242 10L Waste Bag is substantially equivalent to the LN246 10L Waste Bag.

These changes do not affect the intended use or alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 2002

Mr. John Sokolowski
Vice President, Regulatory Affairs
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9144

Re: K014083
Trade Name: Haemonetics® Cell Saver® 5 Autologous Recovery System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC
Dated: December 10, 2001
Received: December 11, 2001

Dear Mr. Sokolowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

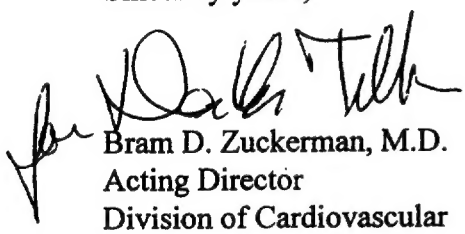
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.8 Indication for Use Statement

510(k) Number: K014083

Device Names: Haemonetics Cell Saver 5 Autologous Blood Recovery System

Haemonetics List No. 291A Disposable Set: Haemonetics Corporation Basic Mini Volume (70 mL) Cell Saver 5 Bowl Set

Haemonetics List No. 242 10L Waste Bag

Indications for Use: The Cell Saver 5 Autologous Blood Recovery System is intended for use to recover blood shed during or subsequent to an operation or as a result of trauma, processing the blood by a centrifugation and washing procedure, and pumping this processed red cell product to either a bag for gravity reinfusion into the patient or to the arterial line of an extracorporeal circuit for reinfusion into the patient. The intended use of the Sequestration Protocol is to collect an autologous, preoperative, platelet rich plasma product for reinfusion to the same patient within 6 hours of collection.

The LN291A is intended to be used with the CS5 Autologous Blood Recovery System for cell salvage protocols.

The LN242 is intended to be used with the CS5 Autologous Blood Recovery System as a replacement waste bag.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014083